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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/011,797	07/23/1998	MARC PARMENTIER	VANMA72.001A	1370

7590 06/25/2004

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/011,797

Applicant(s)

PARMENTIER ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,37,38,40-42,47 and 59-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64-66 is/are allowed.
- 6) ☒ Claim(s) 35, 37-38, 40-42, 47, 59-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Formal Matters

Claims 35, 37-38, 40-42, 47, 59-66 are pending and under consideration.

Response to Amendment

Applicant's arguments filed 04/01/2004 have been fully considered but they are persuasive in part, for the reasons set forth below.

The rejection of claim 60 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,837,809 (Grandy et al. 1998), has been obviated by Applicant's showing under 37 CFR 1.608. However, Applicant is advised that there are remaining issues with regard to this claim, and after those issues are resolved, the Examiner will propose an interference, see MPEP § 2307.02.

The rejection of claims 40, 47, 59, 60 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,837,809 (Grandy et al. 1998), has been obviated by Applicant's showing under 37 CFR 1.608. However, Applicant is advised that there are remaining issues with regard to these claims, and after those issues are resolved, the Examiner will propose an interference, see MPEP § 2307.02.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 37-38, 40-42, 47, 59, 60 stand rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding an amino acid of SEQ ID NO: 2-4; a nucleic acid consisting of the sequence as set forth in SEQ ID NO: 1; or a

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polypeptide consisting of SEQ ID NO: 2, 3, 4; or a nucleic acid which consists essentially of nucleic acid sequences which encode SEQ ID NO: 2-4 wherein the encoded polypeptide binds ORL1 receptor; or a nucleic acid molecule which consists essentially of SEQ ID NO: 1, wherein the encoded polypeptide binds ORL1 receptor; or a polypeptide consisting essentially of SEQ ID NO: 2, 3, 4, wherein the polypeptide binds ORL1 receptor, does not reasonably provide enablement for a nucleic acid which consists essentially of nucleic acid sequences which encode SEQ ID NO: 2-4; or a nucleic acid molecule which consists essentially of SEQ ID NO: 1; or a polypeptide consisting essentially of SEQ ID NO: 2, 3, 4; for reasons of record set forth in the Office Action of 10/7/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of record set forth that since the claims are drawn to polynucleotides and polypeptides which are defined in terms of open language, i.e. the polynucleotides or polypeptides "consist essentially of..." the claims are drawn to a genus of polynucleotides and polypeptides. However, insufficient guidance is provided as to which of the myriad of polynucleotide and polypeptide species encompassed by the claim will retain the characteristics of the sequences which are defined as SEQ ID NO: 1-4, since no function is set forth for the encompassed polynucleotides and polypeptides. It would require undue experimentation for one of skill in the art to make and use the claimed polynucleotides and polypeptides since no function is set forth. There are two issues here, the first is that Applicant must teach how to make and use the invention. Here, there is no use for a polynucleotide encoding a polypeptide that does not function as a ligand of ORL1 receptor, nor is there a use for a polypeptide that does not function

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as an ORL1-ligand. In order for the polypeptides and polynucleotides to have a use, the encoded polypeptides must bind to ORL1 receptor; therefore the claim needs to include the limitation wherein the encoded polypeptides will bind ORL1. The second issue is that it would require undue experimentation to make polynucleotides and polypeptides that do not bind to the ORL1 receptor, since there is no function set forth for the encompassed polynucleotides and polypeptides. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Since the claims encompass variant polynucleotides and polypeptides, and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to make and use the claimed polynucleotides and polypeptides.

Claims 35, 37-38, 40-42, 47, 59, 60 stand rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Action of 10/7/2003. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

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The rejection of record set forth that because of the use of the open language in the claims, the claims encompass polypeptides and polynucleotides having one or more additions made to their sequences. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, there is no function set forth for the encompassed polynucleotides and polypeptides. There is not written description for the polynucleotides and polypeptides because there is not a correlation between functional characteristics and structural features since there is not a function set forth.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The preamble of claim 61 is directed to a method of identifying an agonist or antagonist of ORL1 receptor. However, the method steps would only identify a ligand that binds the ORL1 receptor, since it only measures binding, and would not necessarily identify an agonist or antagonist of the receptor. Thus it is not clear what the method as a whole is directed to, and the metes and bounds of the claim cannot be determined. Claims 62-63 are rejected insofar as they depend on claim 61.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene (1991).

The Stratagene catalogue teaches the use of random 9-mers capable of hybridizing to all gene sequences. The random primers meet the limitations of claims 35 and 37 in that said primers are isolated DNA which are complementary to a sequence as set forth in SEQ ID NO: 1. Applicant argues that the phrase “complementary strand” refers to a nucleic acid strand which is complementary to the sequence of SEQ ID NO: 1, not a fragment of SEQ ID NO: 1. However, the claims recite “a complementary strand”, which covers many complementary strands, including fragments. If the claim is meant to be drawn to the full-length complementary strand it should be amended to recite “...the complementary strand” or “...the full length complementary strand”. Applicant further argues that the random 9-mers would not bind to SEQ ID NO:1 ,

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however, these primers are designed to bind to all DNA sequences, and it is an inherent property of the random 9-mers to bind to SEQ ID NO: 1.

Conclusion

Claims 64-66 are allowable.

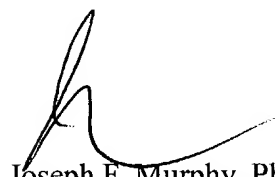
Claims 35, 37-38, 40-42, 47, 59-63 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.

Patent Examiner

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June 21, 2004